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EXAMINER
LONG, SCOTT

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/517,774	MONTARRAS ET AL.	
	Examiner	Art Unit	
	SCOTT LONG	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-10 and 13-15* is/are pending in the application.

4a) Of the above claim(s) *13-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/26/2009 has been entered.

Election/Restrictions

Newly submitted claims 13-15 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

If independent claims 13 and 14 were presented along with claim 10 in originally filed claims, the examiner would have required a restriction election under lack of unity.

Claim 10 is directed to a method of treating disease by cell therapy or gene therapy comprising injecting human or animal stem cells into a subject. The examiner had previously examined an embodiment of claim 10, which encompassed a method of gene therapy comprising injecting a subject with stem cells. The previous action provided an anticipation rejection in which Reid et al. (US-6,069,005, issued May 30, 2000) teach a method of isolating hepatoblasts and a general method of treatment wherein “hepatoblasts can be used in gene therapy” (col.7, line 38).

However, new claims 13 and 14 are clearly directed to regeneration of a tissue (claim 13) and myocardial repair (claim 14). Claims 13 and 14 are embodiments of the applicant's invention which were not previously claimed.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13-15 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Basis for Lack of Unity: Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-2 and 5-10, drawn to a method for preparing human or animal stem cells and a method of treating disease by cell therapy or gene therapy.

Group II, claim 13, drawn to method for regenerating or repairing tissue by transplanting stem cells.

Group III, claims 14-15, drawn to a method for myocardial repair comprising grafting stem cells in the myocardium.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions are drawn to multiple methods, therefore as per 37 CFR § 1.475(a)-(d), applications containing claims drawn to multiple processes of manufacture or uses, only the first recited invention will be considered as having unity of invention (see particularly section (d)). See the following:

37 CFR § 1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

In addition to the reasons cited above, the following reference teaches the technical features of claim 1, as described in the preliminary amendment, a method for preparing stem cells.

Reid et al. (US-6,069,005, issued May 30, 2000) teach a method of isolating hepatoblasts and a general method of treatment wherein "hepatoblasts can be used in gene therapy" (col.7, line 38).

Therefore there is no special technical feature, as required for co-examination and restriction is required because there is no unity of invention or inventive step. A single group must be elected.

Claim Status

Claims 1-2, 5-10 and 13-15 are pending. However, claims 13-15 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claim 4 and 11-12 are cancelled. Claim 1 is amended. Claims 1-2, and 5-10 are under current examination.

Priority

This application claims benefit as a 371 of PCT/FR03/02010 (filed 6/27/2003). The application also claims benefit from foreign application CANADA 2391638 (filed 6/28/2002). The instant application has been granted the benefit date, 28 June 2002, from the application CANADA 2391638.

RESPONSE TO ARGUMENTS

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Applicant's arguments (Remarks, page 7) and claim amendments filed 26 January 2009 regarding the rejection of claims 1 and 7 under 35 USC 102(b) as anticipated by Mignone et al. (WO2001/36482) have been fully considered and they are persuasive.

The applicant has amended claim 1 so as to limit the scope of the instant claims to stem cells that are progenitor stem cells for a tissue selected from the group consisting of skin, heart, and bone tissues. The applicant argues Mignone fails to disclose progenitor stem cells for any of these tissues. The examiner concurs with the applicant's assessment of the teachings of Mignone and finds this argument persuasive.

Accordingly, the examiner withdraws the rejection of claims 1 and 7 under 35 USC 102(b) as anticipated by Mignone et al.

Applicant's arguments (Remarks, page 7) and claim amendments filed 26 January 2009 regarding the rejection of claims 1 and 7 under 35 USC 102(b) as anticipated by DiMario et al. (Experimental Cell Research. 1995. Vol.216, No.2: 431-442) have been fully considered and they are unpersuasive.

The applicant has amended claim 1 so as to limit the scope of the instant claims to stem cells that are progenitor stem cells for a tissue selected from the group consisting of skin, heart, and bone tissues. The applicant argues DiMario fails to disclose progenitor stem cells for any of these tissues.

The examiner disagrees with the applicant's assessment of the teachings of DiMario. The teachings of DiMario are directed to methods for preparing myoblasts from fetal quail and chick muscles and transplanting the myoblasts into host limbs. Myoblasts isolated from muscle may be progenitor stem cells for heart. Therefore, the examiner considers the claim amendment to be insufficient to overcome the instant rejection.

Accordingly, the examiner maintains the rejection of claims 1 and 7 under 35 USC 102(b) as anticipated by DiMario et al.

The examiner reiterates the pending rejection:

Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by DiMario et al. (Experimental Cell Research. 1995. Vol.216, No.2: 431-442).

Claim 1 is directed to a method for preparing human or animal stem cells, said method comprising: cell extraction; mechanical dissociation; enzymatic dissociation; maintaining of the cells obtained, in a specific culture medium for preserving diversity

and plasticity, said method excluding in vitro cell culture, wherein said stem cells are progenitor stem cells for a tissue selected from the group consisting of skin, heart, and bone tissues.

DiMario et al. describe a method of myoblast transplantation, in which the cells are not precultured (i.e. – freshly prepared). (Chicken and quail) muscle tissue is placed in a specific medium (HBSS) and dissociated, firstly by using mechanical means (minced) and then by adding trypsin (page 432, col.1, last parag.). The cells were maintained in culture media containing horse serum, bFGF (differentiation inhibiting factor), are collected by means of filtration, then stored in Hank's Buffered Salt Solution (HBSS) before being injected into a chicken embryo hindlimb buds (page 433, col.1, Cell Transplantation). DiMario teach "maintaining cells in a specific culture medium for preserving diversity and plasticity of the stem cells." For example, DiMario et al. teach isolated myoblast cells were maintained in culture media containing horse serum, bFGF (differentiation inhibiting factor), are collected by means of filtration, then stored in Hank's Buffered Salt Solution (HBSS) before being injected into a chicken embryo hindlimb buds (page 433, col.1, Cell Transplantation). DiMario et al. indicate that "over time, a portion of the myoblasts maintained in vitro irreversibly differentiate before injection." (page 441, lines 25-26). Although some portion of the myoblasts differentiated so that they no longer the plasticity of stem cells, another portion of the myoblasts did not irreversibly differentiate before injection. DiMario et al. teach "myoblasts which still retain high myogenic potential throughout the cell culture period and which are maintained in the cell cycle by culture conditions promptly differentiate

into muscle fibers when removed from the cell culture environment." (page 441, col.1, bottom parag.). After several days, it was possible to note the survival of the cells and their incorporation into the hindlimbs (page 433, Results). Myoblasts isolated from muscle may be progenitor stem cells for heart; therefore, the wherein clause does not distinguish claim 1 from the cited art.

The transplantation method disclosed in DiMario et al. meet the limitations of claim 7.

Accordingly, DiMario et al. anticipated the instant claims.

35 USC § 102/103

Applicant's arguments (Remarks, page 8) and claim amendments filed 26 January 2009 regarding the rejection of claims 1-12 under 35 U.S.C. 103(a) as obvious over Reid et al. (US-6,069,005, issued May 30, 2000) have been fully considered and they are persuasive.

The applicant has amended claim 1 so as to limit the scope of the instant claims to stem cells that are progenitor stem cells for a tissue selected from the group consisting of skin, heart, and bone tissues. The applicant argues Reid fails to disclose progenitor stem cells for any of these tissues. The examiner concurs with the applicant's assessment of the teachings of Reid and finds this argument persuasive.

Accordingly, the examiner withdraws the rejection of claims 1-12 under 35 USC 103(a) as unpatentable over Reid et al.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, and 5-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over DiMario et al. (Experimental Cell Research. 1995. Vol.216, No.2: 431-442) in view of Reid et al. (US-6,069,005, issued May 30, 2000).

Claim 1 is directed to a method for preparing human or animal stem cells, said method comprising: cell extraction; mechanical dissociation; enzymatic dissociation; and maintaining of the cells obtained, in a specific culture medium for preserving diversity and plasticity of the stem cells, said method excluding in vitro expansion of said stem cells, wherein said stem cells are progenitor stem cells for a tissue selected from the group consisting of skin, heart, and bone tissues.

DiMario et al. describe a method of myoblast transplantation, in which the cells are not precultured (i.e. – freshly prepared). (Chicken and quail) muscle tissue is placed in a specific medium (HBSS) and dissociated, firstly by using mechanical means (minced) and then by adding trypsin (page 432, col.1, last parag.). The cells were maintained in culture media containing horse serum, bFGF (differentiation inhibiting factor), are collected by means of filtration, then stored in Hank's Buffered Salt Solution (HBSS) before being injected into a chicken embryo hindlimb buds (page 433, col.1, Cell Transplantation). DiMario teach “maintaining cells in a specific culture medium for preserving diversity and plasticity of the stem cells.” For example, DiMario et al. teach isolated myoblast cells were maintained in culture media containing horse serum, bFGF (differentiation inhibiting factor), are collected by means of filtration, then stored in Hank's Buffered Salt Solution (HBSS) before being injected into a chicken embryo

hindlimb buds (page 433, col.1, Cell Transplantation). DiMario et al. indicate that "over time, a portion of the myoblasts maintained in vitro irreversibly differentiate before injection." (page 441, lines 25-26). Although some portion of the myoblasts differentiated so that they no longer the plasticity of stem cells, another portion of the myoblasts did not irreversibly differentiate before injection. DiMario et al. teach "myoblasts which still retain high myogenic potential throughout the cell culture period and which are maintained in the cell cycle by culture conditions promptly differentiate into muscle fibers when removed from the cell culture environment." (page 441, col.1, bottom parag.). After several days, it was possible to note the survival of the cells and their incorporation into the hindlimbs (page 433, Results). Myoblasts isolated from muscle may be progenitor stem cells for heart; therefore, the wherein clause does not distinguish claim 1 from the teachings of Mario.

In addition, Reid et al. teaches methods of isolating hepatoblasts which encompasses all of the method steps recited by claim 1, except that the stem cells prepared by Reid develop into liver tissues. Reid et al. teaches "cells from day 15 gestation livers were panned against rat red blood cells antibody and the epithelial-enriched cell suspension was plated in a serum-free hormonally defined medium with αMEM as a basal medium" (col.15, lines 47-50). Reid et al. also teach, "in order to isolate fetal liver cells, pregnant rats at the fourteenth day of gestation were euthanized…livers were then dissected from the fetuses…livers were moved to a 50 ml conical centrifuge tube by pipette, gently triturated 6 to 8 times to partially disaggregate the tissue…tissue was resuspended in 50 ml 0.6% collagenase D…gently

triturated…cells suspension was centrifuged and the cells were resuspended in …HBSS-MEM" (col.7, line 54 to col.8, line 16). Reid et al. also teach, "cells before and after sorting were maintained at 4oC and in HBSS-MEM." (col.8, line 55). According to the examiner's reading of Reid et al., the cells were not expanded or differentiated while being maintained in the culture medium.

The examiner has included the teachings of both DiMario and Reid to show that the method steps of instant claim 1 are well known in the art. Regardless of the tissue into which progenitor stem cells develop, the basic scheme of cell extraction, mechanical dissociation, enzymatic dissociation, and cell culture (excluding in vitro expansion) is known in the art of preparing stem cells.

The teachings of DiMario and Reid differ in respect to limitations found in the dependent claims. In particular, DiMario uses a specific culture medium that contains serum, while Reid teaches culturing stem cells in a serum-free medium. Since it is desirable for stem cells intended for transplantation to retain their plasticity, undifferentiated state, Reid also augments their media with differentiation inhibiting factors.

Claim 2 is directed to the method of claim 1, wherein the culture media comprises at least a) a nutritive medium; b) a protective factor; c) hormones; and d) differentiation inhibiting factors. The specification indicates that a "protective factor" can be transferrin (page 9, line 4). The specification indicates that a "hormone" can be insulin (page 9, line 6). The specification indicates that a "differentiation inhibiting factor" can be EGF (page 9, line 17). Reid et al. teach that their minimal essential

medium (MEM) can contain transferrin, insulin, and EGF (col.8, line 9 and col. 9, lines 18, 22).

Claim 5 is directed to a medicinal product comprising the human or animal stem cells, obtained according to the method of claim 1, and one or more additives comprising a specific culture medium devoid of animal serum, the culture medium comprising a) a nutritive medium; b) a protective factor; c) hormones; and d) differentiation inhibiting factors. Reid et al. teach isolated hepatoblasts in MEM comprising transferrin, EGF and insulin. (col.8 , line 9 and col. 9, lines 18, 22).

Claim 6 is directed to a stem cell obtained according to the method of claim 1 which is in a specific culture medium devoid of animal serum, the culture medium comprising a) a nutritive medium; b) a protective factor; c) hormones; and d) differentiation inhibiting factors. Reid et al. teach isolated hepatoblasts in MEM comprising transferrin, EGF and insulin. (col.8 , line 9 and col. 9, lines 18, 22).

Claim 7 is directed to a method of treatment comprising implanting autologous or heterologous animal stem cells, obtained according to the method of claim 1. Reid et al. teach "this invention is further directed to use of hepatoblasts…to treat liver dysfunction…liver transplantation." (col.7, lines 26-32). DiMario discloses a method of myoblast transplantation.

Claim 8 is directed to a cell composition comprising human or animal stem cells, obtained according to the method of claim 1; a specific culture medium devoid of animal serum, the culture medium comprising a) a nutritive medium; b) a protective factor; c) hormones; and d) differentiation inhibiting factors. Reid et al. teach isolated

hepatoblasts in MEM comprising transferrin, EGF and insulin. (col.8 , line 9 and col. 9, lines 18, 22). DiMario discloses a composition of myoblasts in medium having hormones, fibroblast growth factor (a differentiation inhibiting factor) and serum.

Claim 9 is directed to the composition of claim 8, wherein the stem cells have the ability to colonize and the ability to allow functional recovery. Reid et al. teach "hepatoblasts can be injected into the body, such as into the liver or into an ectopic site" (ocl.7, lines 30-31). DiMario teach myoblast transplantation for muscle fiber formation in the developing avian limb (page 432 and 441).

Claim 10 is directed to a method of treating disease by cell therapy or gene therapy, comprising, injecting the human or animal stem cells, obtained by the method of claim 1, into a subject in need thereof. Reid et al. teach, "further, hepatoblasts can be used in gene therapy" (col.7, line 38). Reid et al. teach myoblast transfer therapy (page 441, col.2).

It would have been obvious to the person of ordinary skill in the art at the time of the invention was made to combine the teachings of DiMario and Reid in a method for myoblast preparation.

The person of ordinary skill in the art would have been motivated to make that modification to substitute the cell-free medium of Reid in the method of DiMario. Regarding the rationale for combining prior art elements according to known methods to yield predictable results, all of the claimed elements were known in the prior art and one skilled in the art could have combined the element as claimed by known methods with no change in their respective functions, and the combination would have yielded

predictable results to one of ordinary skill in the art at the time of the invention. Each of the elements (methods for preparing stem cells; methods of culturing stem cells in culture mediums which comprise nutritive medium, protective factors, hormones, and differentiation inhibiting factors, but do not contain serum) are taught by DiMario or Reid and further they are shown to be useful in preparing stem cells which preserve diversity and plasticity. It would be therefore predictably obvious to use a combination of these elements in a method of preparing stem cells which can differentiation in to skin, heart, and bone.

An artisan would have expected success, because both Mario and Reid are successful in preparing stem cells by similar methods.

Therefore the products and methods as taught by DiMario et al. in view of Reid et al. would have been *prima facie* obvious over the products and methods of the instant application.

Conclusion

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Scott Long/
Patent Examiner, Art Unit 1633